

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Kadcyla (ado-trastuzumab emtansine)

CG-DRUG-96

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Kadcyla (ado-trastuzumab emtansine)

APPROVAL CRITERIA

Kadcyla (ado-trastuzumab emtansine) may be approved as a single agent therapy for individuals with metastatic breast cancer who meet all of the criteria (A-D) below:

- A. Individuals have previously received trastuzumab and a taxane, separately or in combination; **AND**
- B. Individuals have either:
 1. Received prior therapy for metastatic disease; **or**
 2. Developed disease recurrence during or within six months of completing adjuvant therapy; **AND**
- C. Individuals whose breast tumors are HER2 positive as documented by one of the following:
 1. Immunohistochemistry (IHC) is 3+; **or**
 2. In situ hybridization (ISH) positive by any of the following:
 - a. Single probe average HER2 copy number greater than or equal to 6.0 signals/cell; **or**
 - b. Dual-probe HER2/CEP 17 ratio greater than or equal to 2.0; **or**
 - c. Dual-probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell; **AND**
- D. Only used in a single line of therapy.

Kadcyla (ado-trastuzumab emtansine) may **not** be approved for individuals who do not meet the criteria listed above.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Use of Kadcylla (ado-trastuzumab emtansine) in combination with other targeted biologic agents or chemotherapy agents may **not** be approved.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Ado-trastuzumab emtansine. In: DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated February 15, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on March 22, 2018.
2. Ado-trastuzumab emtansine Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised April 6, 2016. Accessed on March 22, 2018.
3. Giordano SH, Temin S, Kirshner JJ, et al.; American Society of Clinical Oncology. Systemic therapy for patients with advanced human epidermal growth factor receptor 2-positive breast cancer: American Society of Clinical Oncology clinical practice guideline. J Clin Oncol. 2014; 32(19):2078-2099.
4. Kadcylla [Product Information], South San Francisco, CA. Genentech, July 25, 2016. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125427s0961bl.pdf. Accessed on March 22, 2018.
5. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium™ (electronic version) National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on March 23, 2018.
6. NCCN Clinical Practice Guidelines in Oncology®. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on March 23, 2018.
 - a. Breast Cancer (V.1.2018). Revised March 20, 2018.
 - b. Gastric Cancer (V.1.2018). Revised March 16, 2018.
 - c. Non-Small Cell Lung Cancer (V.3.2018). Revised February 21, 2018.
7. Wolff A, Hammond MEH, Hicks DG, et al. Recommendations for human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline update. J Clin Oncol. 2013; 31(31):3997-4013.
8. Wolff A, Hammond MEH, Schwartz JN, et al. American Society of Clinical Oncology/College of American Pathologists guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer. J Clin Oncol. 2007; 25(1):118-145.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.